

Applicant/Serial No.: Reinhard Koch et al. / 09/308,407  
Filed/Conf. No. July 8, 1999 / Conf. No. 6096  
Examiner/Group: Michael C. Miggins / 1772  
Amendment mailed: 4 / 15 / 2005  
Attorney File: RO0230US.RCE (#90568)

### **REMARKS**

Original claims 9-17, which are the subject of an appeal of the parent application, have been canceled, and new claims 18-29 have been added. The new claims have a number of limitations which are believed to render these claims in allowable form.

Claim 18 defines a packaging system composed of composite packaging material for the sealed enclosure of a product, the product having active ingredients which are possibly volatile and/or ancillary substances. The composite material is characterized in that it has no significant uptake of active ingredients and no or reduced interactivity with the active ingredients and the ancillary substances. The packaging material includes layers defining a space for holding the product, the layers including barrier layers on opposite sides of the product for forming a barrier against volatile active ingredients, and heat-sealing lacquer layers. Sealing area surfaces are provided on the layers adjacent the space for holding the product, and sealing area surfaces extend around the space to which the heat-sealing lacquer layers adhere. The heat-sealing lacquer layers (1) are initially in a liquid phase applicable with conventional simple printing machines, (2) enable an insignificant uptake of the active ingredient, (3) have a weight per unit area in the range of between 1 and 15 (g/m<sup>2</sup>), and (4) establish adhesive forces after heat activation to form an adhesive layer having an adhesive strength in the region of the strength of the packaging material.

Claim 18, the only independent claim in the application, is patentably distinguishable from each of the references cited against the parent application. These references consist of U.S. Patent No. 3,938,659 (Wardwell), U.S. Patent No. 5,077,104 (Hunt et al.), U.S. Patent No. 5,447,772 (Flieger) and U.S. Patent No. 5,698,217 (Wilking).

Wardwell discloses a bonding system for packaging sterilized products and has a substrate coated with a layer of blush lacquer. A heat-seal adhesive is applied on the lacquer, and the package is then sealed and sterilized. Heat is applied to the periphery of the package to bond the heat-seal material. Wardwell is not used for packaging a product having active, possibly volatile ingredients and does not have barrier layers against the volatile, active ingredients. Whereas as the heat-sealing layer of the present invention can be applied with a conventional printing machine, only the blush lacquer may be applied by printing in Wardwell (col. 5, lines 15-17) but not the heat-seal material. In Wardwell, the heat-seal material is applied as a hot-melt to the surface of the dry, blush lacquer or in solution or suspension and precipitated upon the evaporation of a vehicle (col. 5, lines 41-45).

The heat-sealing lacquer layer set forth in claim 18 of the instant application is applied in thin layers, having a weight per unit area in the range of between 1 and 15 g/m<sup>2</sup>. Wardwell is not concerned with this aspect of the present invention and makes no disclosure in its regard. Finally, present claim 18 recites that the strength of the adhesive is in the region of the strength of packaging material, i.e., very strong, whereas in Wardwell, the strength of the heat-seal material is not an issue since the Wardwell package is opened by rupturing the blush lacquer and not the heat-seal material.

Hunt et al. was only cited in the parent application for its disclosure of a barrier layer on the product side to which barrier there is applied a heat-sealing material and wherein the barrier layer comprises aluminum. However, Hunt et al. does not relate to the other limitations described above with respect to Wardwell, and Hunt et al. is silent with respect to being a barrier layer against anything other than nicotine. There is no suggestion that Hunt et al. enables an insignificant uptake of active ingredients in pharmaceuticals as does the present invention and as set forth in claim 18. It is, therefore, respectfully submitted that Hunt et al., taken alone or with Wardwell, does not render the claims nonpatentable under either 35 U.S.C. 102 or 103.

Flieger was cited for its teaching of a packaging system wherein the heat-sealing layer comprises an ethylene/methacrylic acid dispersion, although it was stated that Flieger does not disclose a heat-sealing layer displaying no measurable active ingredient uptake and wherein the heat-sealing layer comprises a chemical composition which is insufficiently inert to nicotine. Flieger does not disclose the various limitations cited above with respect to Wardwell. Flieger is not directed to the packaging of pharmaceuticals and does not relate to the uptake of the active ingredients of pharmaceuticals. Flieger does not provide a heat-sealable package, but rather to resealable bonds. It is, accordingly, respectfully submitted that Flieger does not suffice, alone or with Wardwell or Hunt et al., to render the present claims unpatentable under either 35 U.S.C. 102 or 35 U.S.C. 103.

Wiling was cited for its teaching of a packaging system comprising a layer within an area which is enclosed by the sealing layer, the enclosed layer entering into interreaction with the packaged product, and wherein the enclosed layer is formed by a moisture-absorbent layer. First, Wiling does not disclose the limitations discussed above with respect to Wardwell. Furthermore, Wiling teaches a desiccant package for transdermal therapeutic systems having a special desiccant compartment which is separated from the compartment containing the transdermal therapeutic system. Wiling does not suggest or teach a desiccant layer which interacts with the packaged product, as is set forth in the independent claim in the RCE application. Wiling discloses a desiccant package which does not touch or interact with either the transdermal therapeutic system or its active substance, rather than a layer material as set forth only in claim 28 of the present application.

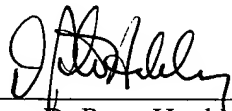
For the foregoing reasons, it is respectfully submitted that the present claims are patentably allowably over the references of record, and it is respectfully requested that these claims be allowed.

The Examiner is invited to telephone the undersigned if an interview would expedite the prosecution of the present application.

Lastly, it is believed that no fees are required for the filing of the claims in this Preliminary Amendment; however, if upon a further review the Examiner deems any fees are necessary, please charge the same to applicants' attorney's Deposit Account 08-2441.

Respectfully submitted,

By: \_\_\_\_\_

  
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